NON-MARRING SPINAL ROD CURVING INSTRUMENT AND METHOD FOR USING SAME

CROSS REFERENCE TO RELATED APPLICATIONS

The present application is a continuation-in-part of co-pending U.S. Patent Application Serial No. 10/138,693 filed May 2, 2002 which is fully incorporated by reference herein.

FIELD OF THE INVENTION

The present invention is related to the curving of surgical rods such as rods that are implanted into a patient's back.

BACKGROUND OF THE INVENTION

Hundreds of thousands of people, both young and old, suffer from a variety of spinal curvature deformities including scoliosis, kyphosis and loss of lumbar lardosis. More severe spinal curvature conditions may require surgery whereby one or more strong yet light weight surgical rods, typically made of a titanium alloy or surgical stainless steel, are inserted into the patient's back to assist in the fusion of the spinal column for aligning the spine in a desired configuration. Such rods are used to realign a patient's spine and maintain it in such a realigned orientation while allowing the patient to resume substantially normal activities. Accordingly, such surgical rods must be at least as strong as the bones to which they are attached, and additionally must be extremely durable. However, these rods also must be able to be shaped to the desired contour so that they properly align the patient's spine.

Thus, before implanting such a surgical rod in patient, it is desirable to curve the surgical rod to better fit the patient's current spinal curvature and/or desired spinal curvature. While a variety of surgical rod bending devices have been developed to shape a surgical rod prior to inserting it into the human body, these devices are plagued with a variety of shortcomings. For example, many of these devices require great force to bend the surgical rod and are thus tedious and inconvenient for the user. Further, because of the material comprising the surgical rods must be resistant to deforming, these devices

typically fail to curve the surgical rod accurately and/or smoothly. For example, these devices typically exert the bending forces on relatively small discrete cross sectional locations along the rod to thereby make a series of small but discrete angular bends along the surgical rod. Such bends may be characterized as follows: as the length of the rod is traversed, immediately prior to encountering a bend, the curvature of the rod has some initial curvature and the curvature of the rod typically rises, from this initial curvature, to a maximum curvature at the apex of the bend, and then returns to a lower value for a portion of the rod immediately following the bend apex. Moreover, the rise in the curvature at the bend is, say, two to three times the initial curvature, and likely two to three times the rod curvature following the bend apex.

However, regardless of the characterization of such a bend, the application of bending forces at relatively small cross sectional locations discretely spaced along the rod's length induces weaknesses in the durability of the rod at such bending locations. Moreover, the relatively abrupt curvature changes associated with such bends are also believed to contribute to rod failure after being surgically implanted in a patient. Although not being bound by any particular theory as to the failures of such rods, it is believed that, e.g., vibrations and stresses induced in the rod by normal or typical patient movements and jarring do not effect the rod uniformly. In particular, such vibrations and/or stresses are not transmitted as easily across such a bend. Thus, there is a disproportional amount of the forces of such vibrations and/or stresses expended at such bends rather than being transmitted throughout or along the rod and desirably dissipated through the ends of the rod. Accordingly, over months or years, such vibrations and/or stresses can cause such a rod to break where such a bend has been induced into the rod.

In addition, such prior art rod bending devices may induce undesirable rod surface abnormalities such as fractures, notches, marring or blemishes in the surface of a surgical rod during bending. Such surface abnormalities can also compromise the durability of an implanted rod. In particular, a rod implanted with such a surface abnormality can, over time, break due to, e.g., vibrations and/or stresses of normal patient activities being disproportionately absorbed by rod areas having such abnormalities.

Moreover, despite the fact that the patient's spine may be abnormally curved

along multiple dimensions (and accordingly can often require correction in multiple directions), the prior art devices do not easily allow the user to bend the surgical rod along different axes.

Thus, it would be desirable to have a surgical rod shaping apparatus and method of use, wherein such a surgical rod can be curved, e.g., during a surgical implant procedure, without inducing localized weaknesses in the rod, and without inducing abrupt curvature changes in the rod due to bending forces being focused on one or more discrete locations along the length of the rod. In particular, it would be desirable to provide smooth continuous curves in such rods. Moreover, it would be desirable to curve such surgical rods without introducing surface abnormalities in the rod. The present invention is intended to overcome at least the above described problems with prior art surgical rod shaping (e.g., bending) apparatuses and methods.

SUMMARY OF THE INVENTION

The present invention is a surgical rod curving apparatus and method for providing curves in surgical rods that, e.g., are implanted into patients to reduce a severity of a spinal abnormality. In particular, the present invention induces smooth, curves into surgical rods, such that there is a reduction or elimination of material stress points (also denoted in the art as "stress risers") in the rods. More particularly, the present invention applies a rod curving force or tension laterally to such a rod while the rod is moved in a substantially transverse direction that corresponds to the length of the rod. Thus, a force for contouring a rod is uniformly distributed over a length of the rod rather than applied to discrete spaced apart points along the rod's length. That is, the force is successively applied to a continuous line of points along a desired lengthwise extent of the rod (denoted herein as the force being "rolled along the rod"). Thus, for example, the force may be moved along the length of the rod by, e.g., moving the rod lengthwise through the desired length while the force is stationary thereby continuously applying the force to points along the rod. Accordingly, the present invention induces a curving force into the rod, where the force is applied over a sufficient lengthwise extent of the rod so as to provide a smooth curve with substantially no points on the rod where

vibrations and/or stresses can induce localized weaknesses in the rod.

Moreover, it is an aspect of the invention that when inducing such curves that do not have localized weaknesses (e.g., bends and/or surface abnormalities), a rod is deformed in a manner that is more similar to an extruding action than a bending action in that the structural integrity of the rod is maintained. In particular, the curving of a surgical rod with the present invention may be an iterative process, wherein each of a plurality of the lateral curving forces is applied continuously across a length of the rod (as described above) to successively curve the rod more. Moreover, each such lateral curving force may not be sufficient, upon first contact with the rod, to induce a deflection in the rod that would not produce a bend in the rod which will stay once the force is removed. That is, upon first contacting the rod, such a rod curving force may only be sufficient to deflect the curvature of the rod without inducing a bend that would be retained in the rod upon removal of the force. However, it is an important aspect of the present invention that as such a lateral curving force is rolled along the rod, a deformation of the rod occurs which is retained once the force is removed. Accordingly, by iteratively rolling a plurality of such forces over a particular portion of the rod, a desired curve can be created in the rod.

Other features and benefits of the present invention will become evident from the accompanying drawings and the detailed description hereinbelow.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of a fully assembled first embodiment of the surgical rod curving apparatus 10 of the present invention.

Fig. 2 shows the apparatus 10 of Fig. 1 with the top plate 68 removed.

Figs. 3A and 3B show the apparatus 10 of Fig. 1 with the top plate 68 and the driving roller subassembly 44 removed (Fig. 3A), and flipped over to show their lower sides (Fig. 3B).

Fig. 4 shows a more detailed view of driving roller subassembly 44.

Fig. 5 shows a more detailed view of the assembled rod contacting components of the rod curving apparatus 10 with the top plate 68 removed.

Fig. 6 shows a top view of the surgical rod curving apparatus 10A which is an alternative embodiment of the present invention.

Fig. 7 shows a perspective view of the housing 312 for the invention embodiment shown in Fig. 6.

Fig. 8 shows an embodiment of an alignment handle 190A used to grip an end of a rod 14 when curving the rod according to the present invention; this figure also shows an adjustment arm 180A that can be used to apply additional leverage in turning the adjustment knob 60A (Fig. 12), and/or, in tightening or loosening the grip 498 of the alignment handle 190A.

Figs. 9A through 9C shows various views of the driving roller 120A and components thereof.

Fig. 10 shows the underneath side 316 of the base 16A for the apparatus 10A (Fig. 6).

Fig. 11 shows the driving roller subassembly 44A partially disassembled so that certain interior components can be shown.

Fig. 12 shows an external view of the driving roller subassembly 44A and a perspective view of the adjustment knob 60A.

Fig. 13 shows, for each of the counter rollers 140A, an exploded view of the components used for rotatably providing counter roller within the counter roller slot 344.

DETAILED DESCRIPTION OF THE INVENTION

Figs. 1 and 2 show an embodiment of a surgical rod curving apparatus 10 according to the present invention, wherein the apparatus 10 is supported on a substantially horizontal surface 12. In describing the rod curving apparatus 10, all references hereinafter indicative of an orientation such as vertical, horizontal, upper, lower are to be understood as referring to the rod curving apparatus 10 as oriented in Fig. 1 relative to the surface 12. Thus, a components closer to the surface 12 may be described as being "lower", components further from the surface 12 may be described as being "upper", orientations substantially perpendicular to the surface 12 will also be denoted as "vertical", and orientations parallel with the surface 12 will also be denoted as

"horizontal". However, as one skilled in the art will recognize after reviewing the description and the drawings herein, other embodiments of the rod curving apparatus 10 may be provided in other orientations such as being attached to a vertical surface.

The surgical rod curving apparatus 10 includes a base 16 of, e.g., 304 stainless steel. The base 16 is approximately eight inches by four inches and has a center portion 20 that is raised above the surface 12 by approximately three to five inches. Secured to the side (denoted the "upper side" herein) of the center portion 20 furthest from, and facing away from, the surface 12 is a frame 24 of, e.g., 304 stainless steel. The frame 24 includes a lower plate 28 fixed to the upper side of the center portion 20, and two side plates 32 (Fig. 2) that are attached to the lower plate 28. The side plates 32 have a vertical width of approximately one inch to 1 ½ inches, a horizontal length of approximately three to four inches, and a thickness of approximately 1/8 inch.

Attached to the frame 24 is a force inducing assembly 36 (Figs. 1, 2 and particularly 3) for providing a force in the direction of arrow 40 (Fig. 2) for thereby urging a curve driving roller subassembly 44 (also denoted herein as a driving roller subassembly) into contact with a rod 14 for administering a rod curving force laterally to the rod 14. The force inducing assembly 36 includes a threaded anchor 48 that is secured to the lower plate 28 by, e.g., welding thereto. Through a central portion of the anchor 48 is a threaded bore 52 that is generally aligned with the arrow 40. Within the bore 52 is a mating threaded shaft 56 which at one end is attached to an adjustment knob 60 by which the shaft 56 may be rotated so that the opposite end 64 of the shaft 56 is movable both in the direction of arrow 40, and in the opposite direction. Note that the center portion 20 is raised sufficiently so that the adjustment knob 60 is easily rotated by a user without the surface 12 interfering with such rotations. In particular, the lowest portion of the adjustment knob 60 is at least ½ inch from the surface 12, and preferably between ½ and ¾ of an inch. However, the adjustment knob 60 has a sufficiently large diameter so that a user can, in many rod curving adjustments, grip the adjustment knob and manually turn it. Thus, in the embodiment of Fig. 1, the adjustment knob 60 has a diameter of approximately 2 to 2¼ inches.

Figs. 3A and 3B shows the rod curving apparatus 10 partially disassembled so

that certain interior components can be shown. In particular, a top plate 68 (which in Fig. 1 is attached as a top cover of the apparatus 10) is shown flipped over. Additionally the driving roller subassembly 44 is shown flipped over from its operative position when the rod curving apparatus 10 is fully assembled. Thus, also shown in Fig. 3B is the side 72 of the driving roller subassembly 44 having the two gears 76 and 80 thereon, and that faces the recessed and/or cut out portions 84 of the lower plate 28 when the apparatus 10 is fully assembled. Moreover Fig. 3A shows the edges 88 and 92 of the recessed portion 84, wherein these edges follow the contours of various portions of the side 72 together with contours of the gears 76 and 80. When the rod curving apparatus 10 is fully assembled, the portion of the shaft 56 protruding from anchor 48 near the shaft end 64 extends through slot 96 of the bifurcated shaft connector100 and contacts the plate 104 (best shown in Fig. 4). Moreover, a groove 102 in the shaft 56 mates with the bifurcated shaft connector100 so that the groove fits within the slot 96 and remains within the slot during operation due to the fact that the diameter of the shaft outside of the groove is larger than the slot 96. Additionally, the groove 102 is positioned on the shaft 56 so that the extent of the shaft from the groove to the shaft end 64 is of sufficient length so that the shaft end 64 exerts substantially all of the forces for curving a rod 14 against the plate 104. Thus, upon rotating the adjustment knob 60 to lengthen the portion of the shaft 56 protruding from the same end of the anchor 48 as the shaft end 64, the shaft end 64 presses against the plate 104 thereby urging the driving roller subassembly 44 in the direction of arrow 40 (i.e., toward the rod 14). Conversely, upon rotating the adjustment knob 60 in the opposite direction to thereby shorten the portion of the shaft 56 protruding from the same end of the anchor 48 as the shaft end 64, the groove 102 and its mating shaft connector100 move away from the rod 14 (i.e., in the opposite direction from arrow 40). Accordingly, the entire driving roller subassembly 44 moves in the opposite direction from arrow 40, thereby reducing a curving tension on a rod 14 being curved, and/or creating a (wider) gap between the driving roller subassembly 44 and the rod 14.

As Fig. 4 shows, the driving roller subassembly 44 also includes two substantially parallel alignment plates 108 and 112 which are attached to one another in a fixed spaced apart relationship by, e.g., at least one connector 116 for securing the alignment plates

108 and 112 together by, e.g., by welding. Additionally, the driving roller subassembly 44 includes a driving roller 120 that is rotatable on an axle 124 (Figs. 2 and 5), wherein the driving roller 120 contacts a rod 14 to be curved and exerts a curving force thereto as will be more fully described hereinbelow. Note that such a rod curving force may be in the range of 2,000 pounds, and accordingly, to assure the durability of the driving roller 120, it may be manufactured from 440C stainless steel, as one skilled in the art will understand. Referring to the axle 124, it is journaled into each of the alignment plates 108 and 112. There are bearings 126 provided on the axle to allow rotation of the driving roller 120. these bearing 126 are non-sealed non-lubricated bearings which are shrink fitted to the axle 124. However, sealed bearing may also be used if they are of a type that can be sterilized by, e.g., autoclaving, without degrading. Note that the gear 80 is fixedly attached to an end of the axle 124 for thereby rotating the driving roller 120 when the gear 80 is urged to rotate by a counter rotation of the gear 76. The gear ratio of the gear 76 to gear 80 may be in a range of 2:1 to 5:1, and more preferably 3:1. Moreover, note that the gear 76 is fixedly attached to an end of an axle 128 which is journaled into each of the alignment plates 108 and 112, and wherein the opposite end of the axle 128 has a crank 132 attached thereto, but offset from the alignment plate 112 with a spacer 134 therebetween. The crank 132, in turn, includes a grip 136 by which a user may rotate the axle 128 and thereby rotate the driving roller 120.

In Figs. 1, 2 and particularly 5, these figures also show two counter rollers 140 whereby a surgical rod 14 is held between the driving roller 120 on one side of the rod, and the counter rollers on another side of the rod. Accordingly, the counter rollers 140 provide counter forces to the rod curving force induced in a rod 14 by the driving roller 120 when this latter roller is urged in the direction of arrow 40 (Fig. 5) and thereby inducing the rod to deflect into the void space 142 between the counter rollers 140. In one embodiment, the driving roller 120 may have an outside diameter of approximately 1 to 1 ¼ inches, and more particularly, 1.186 inches. Note that, as with the driving roller 120, the counter rollers 140 may be manufactured from a more stress resistant material than other components of the present invention. In particular, the counter rollers 140 may be also composed of 440C stainless steel.

Each of the counter rollers 140, and the driving roller 120 includes a respective channel about its circumference for retaining a rod 14 therein. In particular, the counter rollers 140 have channels 146 and the driving roller 120 has a channel 150. Currently, surgical rods 14 have a circular cross section with a diameter of approximately 1/4 to 3/16 inch, and, in the present embodiment, each of the channels 146 and 150 is configured to securely grip each rod 14 without marring or blemishing it. Thus, it has been determined by the applicants that appropriate gripping without marring or blemishing rods 14 occurs when each of the channels 146 and 150 have a contour that follows the cross sectional contour of such rods up to a maximum channel width of approximately the diameter of such rods, and such channels have a depth of approximately the radius of such rods. However, it is important to note that the present invention is not limited to surgical rods 14 having a circular cross section. In fact, for substantially any surgical rod having a convex cross section appropriate channel 146 and 150 contours can be provided. However, note that the channel 146 may be differently shaped from the channel 150. As a simple example, if there is a rod 14 having an isosceles triangular cross section, then in one embodiment, the channels 146 may be substantially flat in cross section for contacting an entire width of a side of the rod 14. However, such alternatively shaped channels 146 may also have a small lip on side of the flat portion of the channel for assuring that the rod remains in the channel during a rod curving operation. Alternatively, for rods 14 with such triangularly shaped cross sections, the channel 150 may have a substantially "V" cross section for thereby mating with a portion of the rod about an edge on the rod corresponding with a vertex of the rod's triangular cross section. One skilled in the art will appreciate that other rod cross sectional shapes can be readily curved by an embodiment of the present invention. For example, for a given rod 14 cross section size and shape, a corresponding driving roller 120 and counter rollers 140 can be provided having channels 146 and 150, respectively, with cross sectional shapes that substantially mate with the cross sectional shape of the given rod 14 to be curved. Thus, embodiments of the surgical rod curving apparatus 10 may be provided for rod 14 having, e.g., hexagonal, elliptical, or trapezoidal in shape.

The counter rollers 140 are sandwiched between retaining plates 170, wherein

each of the counter rollers is secured to the retaining plates 170 by a corresponding cylindrical vertical shaft (not shown) traversing the space between the retaining plates. In particular, each counter roller 140 is journaled on its corresponding shaft for rotating while maintaining a rod 14 to be curved at a substantially constant offset from the shaft about which it rotates. Note that the dimensions of the retaining plates 170 are approximately 1¼ x 4 x ¼ inches, the shafts about which the counter rollers 140 rotate are approximately 3 to 4 inches apart (and more preferably 3 to 3½ inches apart), and the counter rollers 140 as well as the driving roller 120 are approximately 1¼ to 1 ¾ inches in diameter and approximately 3/8 to 3/7 inches thick. Moreover, it is important to note that variations from these dimension ranges are within the scope of the present invention. For example, the counter rollers 140 may be spaced as closely as about 2 inches if, e.g., the diameter of the counter rollers and the driving roller 120 is appropriately reduced to, e.g., ¾ to 1 inch. However, with such smaller dimensions there is an increase in the force required to curve a rod 14, and with the smaller diameter driving roller 120 there is a greater chance of accidentally inducing a pronounced bend in a surgical rod 14. Nevertheless, for surgical rods 14 of smaller diameter than ¼ inches, and/or for inducing smooth rod curves of greater curvature, such a reduced dimension embodiment of the present invention may be appropriate.

As noted above, the majority of the surgical rod curving apparatus 10 may be made from stainless steel for strength, durability, and for repeatedly withstanding sterilization. However, other materials may also be used such as carbon or graphite compounds, ceramics or plastics, in some cases depending upon the strength requirements desired in a particular rod curving apparatus component. For example, the following components: the base 16, the grip 136, the top plate 68, the spacer 134, and/or the adjustment knob 60 may not be subjected to as extreme forces and/or stresses as the forces generated on the rod curving force and counter force generating and conducting components (e.g., the force inducing assembly 36, the curving force conducting components of the driving roller subassembly 44 and the counter rollers 140 together with their retaining plates 170). Thus, one or more of the components that do not experience the rod 14 curving forces/stresses may be made of, e.g., an appropriate

durable plastic, a graphite composite and/or other material that both does not degrade during a sterilization process (e.g., autoclaving), and is acceptable for use in the context of a surgical procedure (e.g., is non-toxic and does not compromise the sterile conditions of an operating room). In particular, although the embodiment of the rod curving apparatus 10 in Figs. 1-5 is not excessively heavy (e.g., about 5.5 pounds), a lighter embodiment may be provided by manufacturing at least some components, such as those identified above, out of one or more materials rather than stainless steel. Moreover, by providing a lighter embodiment of the present invention, additional conveniences may be more easily provided without the surgical rod curving apparatus 10 becoming unwieldy. For example, table clamps and/or fittings may be integrated into the embodiment shown in Figs. 1-5 so that the apparatus 10 is less prone to move during a rod 14 curving process.

Referring again to Fig. 1, this figure also shows an adjustment arm 180 that is insertable into any one of a plurality bores 184 provided about the circumference of the adjustment knob 60, and in particular, between four and eight equally spaced such bores about the adjustment knob circumference. The adjustment arm 180 allows a user to more easily rotate the shaft 56 in the direction for thereby moving the driving roller 120 laterally into a rod 14.

Additionally, Fig. 1 shows a handle 190 for attaching to the end of rods 14 so that during a curving of such a rod by the present invention, the rod can be maintained in a desired orientation. In particular, upon applying repeated curving operations to a rod 14, the rod may tend to twist somewhat about its longitudinal axis and thus the resulting curve may be in an undesirable plane or the resulting curve may be non-planar when a planar curve is desired. The handle 190 includes a hand grip 194 by which a user can orient a rod being curved, and a rod holding portion 198 for fixedly securing a rod 14 and the handle together. The rod holding portion 198 includes a rod insertion bore 204 for inserting rods 14 therein, and a wing nut 208 that threads into a mating threaded opening 212 that: (a) is perpendicular to the rod insertion bore 204, and (b) opens into the rod insertion bore so that the threaded end of the wing nut can contact a rod 14 therein and secure the handle and the rod together. Additionally, the enclosed end of the rod

insertion bore 204, that is toward the hand grip 194, may have a hexagonal configuration for mating with ends of rods 14 that are hexagonal in shape. In particular, many surgical rods 14 made of titanium have such a hexagonal shaped end. Accordingly, by attaching the handle 190 securely to the end a rod 14 so that the handle and the rod rotate and move in unison, a user can prohibit such non-desirable rod twists when curving the rod, or alternatively, the user may induce compound 3-dimensional curves into the rod by purposely changing the orientation of the handle 190 between successive applications of curve inducing forces by the present invention.

In operation a user may first determine the desired curve to induce in a rod 14. The user may wish to identify one or more portions of the rod 14 to be curved by, e.g., providing removable markings on the rod identifying the longitudinal extent(s) of the rod that is to be curved. Subsequently, the user may insert an end of the rod 14 into the rod insertion bore 204 of the handle 190, and secure the rod and the handle together by, e.g., tightening the wing nut 208 in the opening 208 so that the threaded end of the wing nut is secured against the rod. Then the opposite end of the rod 14 is threaded into the rod curving apparatus 10 so that the rod is seated within each of the channels 146 of the counter rollers 140, and additionally, is also seated in the channel 150 of the driving roller 120. Note that to seat the rod 14, the user may have to adjust the position of the driving roller 120 by rotating the adjustment knob 60 so that the rod can threaded into the channels 146 on one side, and the channel 150 on the other. The user then positions the rod 14 within the apparatus 10 so that for (a marked) longitudinal extent of the rod wherein this extent is to be curved, the channel 150 of the driving roller 120 contacts the rod approximately in the middle of this extent. The user may, if not already performed, note and/or change the orientation of the hand grip 194 so that any twisting of the rod 14 during the curving operation may be prohibited and/or is performed as the user desires (e.g., by manually and purposefully twisting the rod as the rod is being curved). In one method of operation, the user may orient the hand grip 194 so that it is parallel to the surface 12 initially, and since it is believed that most rod curves will be planar, in such cases, the user need only hold the hand grip during the rod curving process so as to maintain the grip's parallel orientation to the surface 12. Thus, once the hand grip 194 is

oriented as desired, the user may then rotate the adjustment knob 60 so as to move the driving roller 120 to laterally deflect the rod 14 between the counter rollers 140. It is important to note that preferably the user should turn the adjustment knob 60 (directly or by use of the adjustment arm 180) only enough to cause the rod to deflect wherein the inherent resiliency of the rod would return the rod to its initial straight configuration if the laterally deflecting force exerted by driving roller 120 were removed. Accordingly, for the embodiment of the rod curving apparatus 10 shown in Figs. 1-5, wherein the counter rollers 140 are approximately 3 to 3½ inches apart, the rod 14 is ¼ inch in diameter, and the rod is stainless steel or titanium, under these conditions no more than 1/16 of an inch of deflection is preferred, and more preferably between 1/16 and 1/32 of an inch deflection. Thus, in the embodiment of Figs. 1-5, rod deflection of 1/16 to 1/32 of an inches amounts to approximately ¼ to 1/8 of a turn of the adjustment knob 60.

Accordingly, once the rod 14 is initially deflected by the lateral contact of the driving roller 120, the user then grasps the grip 136 on the crank 132 and revolves the crank and thereby rotate the driving roller 120. Note that there is sufficient tension, due to the resiliency of the rod 14, between the driving roller and rod so that the rod will move substantially synchronously with the rotation of the driving roller 120. That is, the rod 14 moves in a direction corresponding to its longitudinal axis (i.e., in one of the directions identified by the arrow 216 in Fig. 1) without the driving roller 120 slipping or skidding along the surface of the rod. Generally, the user will cause the rod 14 to move in both of the longitudinal axis directions most of the entire length of the extent of the rod to be curved. In particular, the user may cause the driving roller 120 to roll back and forth along the portion of the longitudinal extent, E. of the rod 14 to be curved, wherein the driving roller does not generally roll beyond a point where either of the extremes of the rod extent E come between the rod contact points of the two counter rollers 140. Thus, in the embodiment of Figs. 1-5 this means that the driving roller 120 rolls along the portion of the rod within E that is approximately 1½ to 1¾ inches shorter on both ends of E. Further note that since the driving roller 120 is midway between the two counter rollers 140, substantially the same curve is induced in the rod 14 regardless of the longitudinal axis direction that the driving roller is rolled.

It is important to note that although the deflecting force induced by the drive roller 120 does not bend the rod 14 beyond its resiliency or elasticity limits at any one point along the rod 14, the rod none-the-less retains a deformation when this force rolled along an extent of the rod. Moreover, instead of weakening the rod 14, it is believed that in fact the rod may become sturdier due to the curving process.

Once the driving roller 120 is rolled at once over the appropriate portion of the longitudinal extent E, the user then turns the adjustment knob 60 again to deflect the rod 14 an additional amount (e.g., up to another 1/16 of an inch) and again revolves the crank 132 to thereby roll the driving roller 120 over substantially the same portion of the rod as in the first iteration of rolling above. Thus, curving the rod 14 an additional amount. By repeatedly alternating between causing the driving roller 120 to move further in the direction of arrow 40 and rolling the driving roller over a portion of the rod, the rod is progressively deformed into a desired curve. Moreover, for increasing the curvature of, e.g., a central portion of a particular curve, the longitudinal portion of the rod 14 that is rolled may, in some cases, become progressively less with further iterations.

Note that with each iteration of rolling the driving roller 120 over the rod 14, the user is able to readily view the curving process due substantially to the cut out 220 (Fig. 1). Thus, the user can determine while the rod 14 is engaged in the apparatus 10 whether the desired curve is being provided to the rod. Moreover, if such a curve becomes unacceptable, the user can easily remove the objectionable portion of the curve by removing any driving roller 120 tension being placed on the rod, rotating the rod so that the hand grip 194 is turned 180 degrees (i.e., the rod can be reversed in angular orientation about an axis parallel to a vector tangential to the length of the rod at the handle 190), and then commencing to repeatedly alternate between causing the driving roller 120 to move further in the direction of arrow 40 and rolling the driving roller over a portion of the rod until the undesirable deformation of the curve is removed.

Accordingly, once a desired curve is induced into such a surgical rod 14, the rod may be then implanted into a patient. Note that it is believed that the method and apparatus of the curving surgical rods of the present invention is particularly suited for use in operating rooms during corrective spinal surgery. At least some of the

characteristics that are desirable in this context are that the apparatus 10 may be small (e.g., 4 inches by 8 inches), relatively light weight, easily portable or carried manually by one person, e.g., to various locations within an operating room, does not require substantial technical training that is peculiar to the apparatus. Moreover, it is an additional important feature of the apparatus 10 that the components that fit together (such as the threaded shaft 56 and the anchor 48, and, the rollers and their adjacent components) are sufficiently loosely fitting so that the apparatus can be sterilized in, e.g., an autoclave without disassembling.

In another embodiment of the present invention, the surgical rod curving apparatus 10A is illustrated in Figs. 6-13. Note that for each portion or component (P) of the alternative embodiment of apparatus 10A that has a functionally corresponding component (C) in the rod curving apparatus 10, the labeling for P and C will be identical except that the labeling for P will be suffixed with at least an "A". Thus, there are counter rollers 140A provided in apparatus 10A that correspond functionally to the counter rollers 140 of apparatus 10. Moreover, the dimensions for various components of surgical rod curver 10A are generally similar to those of the surgical rod curving apparatus 10 described hereinabove. In fact, it is assumed that for apparatuses 10 and 10A their corresponding components (i.e., having identical numerical labels except for at least a suffixed "A" on those of apparatus 10A) have substantially the same dimensions (or ranges thereof) unless otherwise stated hereinbelow.

The apparatus 10A is particularly useful in preventing marring of a surgical rod 14 and to make the process of sterilization more effective. Fig. 6 shows a top view of the surgical rod curving apparatus 10A. The apparatus 10A includes a housing 312 (shown in isolation in Fig. 7) that may be manufactured from a single piece (i.e., billet) of stainless steel. The housing 312 provides most of the bulk of the apparatus 10A. Moreover, the housing 312 is configured so that substantially all other components of the apparatus 10A may be easily attached thereto and detached therefrom. Thus, hospital personnel may easily disassemble the apparatus 10A for, e.g., autoclaving, and then easily reassemble the apparatus 10A using at most only a tool such as a screwdriver or Allen wrench for threading various bolts or shafts described herein below. However,

more typically it is believed that no such tools are needed for disassembling the apparatus 10A. Thus, effective sterilization can be provided by disassembling the apparatus 10A without the use of tools. The housing 312 includes a base 16A that is in the shape of a rounded trapezoid (when viewed from above, i.e., Fig. 6) with dimensions of approximately 5 x 4.5 x 7.5 x 4.5 inches wherein the sides corresponding to the 5 inch and 7 inch dimensions are parallel. However, other base 16A shapes and/or sizes may be provided, e.g., an "I" shape, a "T" shape, or an hour glass shape. Moreover, the thickness of the base 16A may be uniform or may vary. For example, in one embodiment, the base 16A may be progressively thicker toward the adjustment knob 60A so that this knob is offset from an operating table a greater distance than would otherwise be the case, and accordingly, provides a more ergonomic angle for turning the knob.

The underneath side 316 of the base 16A may be substantially flat. In one embodiment, shown in Fig. 10, the underneath side 316 includes four circular pedestals 320 of approximately 2.5 inches in diameter that extend outwardly from each corner of the underneath side 316. Such pedestals 320 increase the contact force per square centimeter over an underneath side 316 not having such pedestals and this assists in reducing any shifting of the apparatus 10A on an operating table. Alternative embodiments of the underneath side 316 are also within the scope of the invention. In particular, in some surgical environments, the operating table and/or coverings thereof reduce the friction between the underneath side 316 and the surface which it contacts, and thus additional features and/or components for reducing slippage of the apparatus 10A may be provided. For example, a non-slip elastomeric or foam pad (not shown) may be provided for directly contacting the surgical table underneath the covering, wherein the pad includes recesses of, e.g., hard plastic or metal that face away from the surgical table when the pad is lying flat thereon. These recesses are arranged so that they can mate with the pedestals 320, and more particularly, so that they can mate with the pedestals even though there is a table covering between the pedestals and the recesses. Thus, the frictional grip of the pad to the surgical table provides stability of the apparatus 10A even though the apparatus itself rests upon a low frictional material (i.e., the table covering). Moreover, note that other related embodiments are also within the scope of the invention.

For example, instead of the pad having recesses, the pedestals 320 may have recesses therein which mate with protrusions (of hard plastic or metal) on the surface of the pad facing away from the table (when, as before, the pad is lying flat on the table). In one embodiment, such recesses in the pedestals 320 and their mating pad protrusions have horizontal cross sections that are in the shape of, e.g., a hexagon or a cross wherein the protrusions mate within the recesses to depth of ¼ to 3/16 of an inch.

The underneath side 316 also includes two threaded bores 324 (Fig. 10), substantially adjacent to the shorter parallel side of the trapezoidal base 16A. Each of the threaded bores 324 is used to house a shaft assembly (described below) upon which one of the counter rollers 140A (Figs. 6 and 13) is rotatably provided. When the apparatus 10A is fully assembled, these shaft assemblies are spaced apart 3 to 4 inches (and more preferably 3 to 3½ inches) so that the counter rollers 140A are correspondingly spaced apart (center to center) approximately 3 to 3½ inches. Such a distance is believed to be appropriate for applying the counter forces to the rod bending force provided by the driving roller 120A in that curves induced into the rods 14 can be readily provided by manual operation of the apparatus 10A, and the space taken up by the apparatus 10A on a surgical operating table is not excessive.

Integral with an upper surface 328 (Fig. 6) of base 16A is a rod curving frame 332 that is also included in the housing 312. The rod curving frame 332 includes a counter roller retaining portion 336 for securing the two counter rollers 140A between an upper retaining plate $170A_1$ (best shown in Fig. 7) and a lower retaining block $170A_2$ (wherein $170A_1$ and $170A_2$ have substantially the same functions as the retaining plates 170 in the apparatus 10 of Figs. 1-5; e.g., maintaining the orientation of the counter rollers 140A when rod extruding loads as high as the yield strength of the rod material are placed on these rollers). Note that the plate $170A_1$ and the block $170A_2$ are joined together by a pedestal 340 (Fig. 7), thereby creating counter roller slots 344. The plate $170A_1$, block $170A_2$ and the pedestal 340 must be of a sufficient thickness to maintain the alignment of the counter rollers 140A during surgical rod curving operations, and additionally, to insure that the retaining portion 336 does not also deform due to rod bending operations. In particular, the retaining plate $170A_1$ may be 3/8 to 5/8 inch stainless steel, with the

pedestal 340 being ¾ to 1 ¼ inches in width ("w", Fig. 7).

The housing 312 further includes, as part of the frame 332, a cradle 348 that is generally "U" shaped, wherein the recess 352 (Figs. 6 and 7) of the cradle has a "U" shaped interior wall 356 so that the recess opens towards the roller-retaining portion 336. As described hereinbelow, the cradle 348 provides the alignment for a roller assembly 44A (described below) so that its driving roller 120A contacts each rod 14 being curved at a center point between the counter rollers 140A and with a rod curving force directed laterally and generally traversely to the longitudinal axis of the rod at the point of contact. In particular, the driving roller subassembly 44A provides a force in the direction of arrow 40A (Fig. 6) to administer the lateral curving force to a rod 14 that is held in place by the counter rollers 140A.

The cradle 348 further includes a threaded bore 52A (Fig. 7), wherein this bore is in line with the arrow 40A, and the threads of this bore mate with the threads of the threaded shaft 56A (Fig. 6) described below, wherein this shaft imparts a rod curving force to the roller assembly 44A. Additionally, note that the exterior sides 360 of the cradle 348 adjacent to the opening of the recess 352 are sloped relative to the interior side wall portions 356 adjacent the opening of the recess 352. The sloped angles of the sides 360 provide effective clearance for bending a rod 14 so that cradle 348 does contact the rod and mar its surface.

As shown in Fig. 6, the threaded shaft 56A has, attached to its end extending outwardly from the housing 312, the adjustment knob 60A. The knob 60A is configured so that the base 16A and other parts of the apparatus 10A cannot interfere with the manual rotation thereof. When the apparatus 10A is placed on a relatively flat, even surface, the lowest portion of the adjustment knob 60A may be about at least one inch above the surface upon which the apparatus 10A rests. The opposite end of the threaded shaft 56A includes a smooth cylinder 366 (called herein the "shaft end") that contains a groove 102A (Fig. 12). The groove 102A is used to operably secure the driving roller subassembly 44A to the threaded shaft 56A. In particular, the groove 102A mates with the edges of the slot 96A (Fig. 12) of the bifurcated shaft connector 100A (Figs. 11 and 12). Accordingly, when the shaft 56A is rotated in a first direction, the free end of the

cylinder 366 contacts the contact plate 104A (Fig. 12) for moving the driving roller subassembly 44A toward the rod 14 (i.e., in the direction of arrow 40A), and when the shaft is rotated in an opposite direction, the groove 102A pulls on the portion of the shaft connector 100A contacting the groove, thus causing the driving roller subassembly 44A to move laterally away from the rod 14 (i.e., in the opposite direction of arrow 40A). In particular, for operably securing the shaft 56A to the driving roller subassembly 44A, the groove 102A mates with the slot 96A (Fig. 12) and contacts the contact plate 104A.

In one embodiment, the knob 60A may have a diameter of approximately 2.5 inches and may contain equally spaced bores 184A (Fig. 12) about its circumference, into which an end extension 370 (Fig. 8) of an adjustment arm 180A can be inserted into the bores 184A for turning the adjustment knob 60A substantially any amount the user wishes, such as an 1/8 to ¼ of a turn (as described regarding the apparatus 10 of Figs. 1-5). In particular, ¼ of a turn between rod curving operations may be used for deflecting a stainless steel rod 14 between approximately 1/16 and 1/32 of an inch, and, 1/8 of a turn between rod curving operations for deflecting a titanium rod between approximately 1/32 and 1/64 of a inch between rod curving operations. On the outwardly facing surface 374 of the knob 60A are indicia 378 (preferably etched therein), wherein such indicia are aligned with the bores 184A for use as references during operation of apparatus 10A. Thus, the indicia 378 provide a straightforward way for surgery personnel to easily determine whether, e.g., an 1/8 or a ¼ of a rotation of the knob 60A has been performed.

Figs. 11 and 12 show the driving roller subassembly 44A (partially disassembled in Fig. 11 so that certain interior components can be shown). The driving roller subassembly 44A includes a frame 382 to which substantially all other components of the subassembly 44A are attached. The frame 382 is, in the present embodiment, machined from a single piece of stainless steel without welds and joints that would be difficult to sterilize. The frame 382 includes various machined bores, slots and recesses such as:

(a) a slot 386 (Fig. 11) into which the drive roller 120A fits,

(b) an internal shaft bore (not shown) for the shaft upon which drive roller is mounted and rotates,

(c) an "8"-shaped recess 390 for the gears 76A and 80A (these gears

functioning similarly to the corresponding gears 76 and 80 of the apparatus 10, and having a similar gear ratio),

(d) threaded and tapered holes 394 for receiving threaded screws 396 by which a cover plate 398 is attached to the frame 382 via screw holes 402 in the cover plate,

(e) two alignment holes 406 for receiving projections 410 on the interior surface of cover plate 398 and thereby facilitating in aligning the cover plate on the frame 382, and

(f) an interior shaft bore (not shown), wherein the drive gear 76A is attached to one end, and a crank 132A is attached to an opposite end of this shaft. There are bearings (also not shown) at each end of this shaft to reduce friction and wear between the shaft and the frame 382, and as with all bearings for the apparatus 10A, these bearings are Teflon-impregnated, non-corrosive and autoclaveable (e.g., they do not degrade and remain non-toxic when autoclaved). In particular, all bearings for the apparatus 10A may be made substantially from the plastic, such as polymer EDT 'FA' Material manufactured by DSM Engineering Plastic Products, 2120 Fairmont, Reading, PA 14235. Note that such bearings are FDA-approved for use in surgical equipment.

Thus, a cranking motion applied to the crank 132A is translated into a gear reduced rotational movement of the driving roller subassembly 44A for moving a length of a rod 14 between the counter rollers 140A. In particular, the gear 76A is rotationally driven by the crank 132A, and the gear 80A is rotationally driven by the gear 76A, wherein the gear 80A may rotatably contact the flat bearing 414 (Fig. 11). Note that the bearing 414 is provided in a circular recess of the cover plate 398 such that this bearing protrudes slightly from the surface of the cover plate 398 that faces the gears 76A and 80A, thus substantially precluding contact between the cover plate and the gear 80A. Consequently the gear 80 rotationally drives the driving roller 120A via a shaft not shown. Moreover, note that although the preferably metal shaft connecting the gear 80A to the driving roller 120A is generally cylindrical (i.e., a circular cross section), the shaft

includes a hexagonal cross section near the middle of the shaft's length for engaging a hexagonal hole 418 (Fig. 9A) in the driving roller 120A. Additionally, at substantially each end of this shaft, there is a Teflon impregnated bearing upon which the shaft rotates.

Regarding the crank 132A, it is made from a single piece of metal (e.g., stainless steel). The handle 422 (Fig. 12) of the crank 132A is surrounded by a cylindrical grip 136A made of, e.g., a plastic that is autoclaveable, such as Delron. The cylindrical grip 136A allows a user may comfortably rotate the gear 76A and thereby rotate the driving roller 120A.

Figs. 9A through 9C shows various views of the driving roller 120A and components thereof. The driving roller 120A includes a ring 426 that contacts rods 14 when they are being curved by the apparatus 10A. It is crucial that the material of the ring 426 not introduce surface abnormalities (e.g., marring, blemishes, micro-cracks and/or indentations) in a surgical rod 14 being curved, since as discussed hereinabove, when the rod is implanted into a patient's body, the durability of the rod may be substantially reduced and such rods are likely to break at such rod abnormalities. Accordingly, it is believed that a material that is substantially more elastic than the rods 14, and yet very strong, e.g., having properties substantially similar to a polyetherimide (or a composite thereof, such as a composite that is also glass-reinforced), should be used for the rod contacting portions of the driving roller 120A. Additionally, since the counter rollers 140A can also introduce such abnormalities into the rods 14, it is also important for at least the portions of the counter rollers that contact the rods, these portions should also be made of a similar material. More generally, it is desirable that the rollers 120A and 140A be made of a material (e.g., a plastic, such as a polyetherimide or composite thereof) that satisfies at least some of the following preferred properties (and particularly the tensile, elasticity and temperature properties):

TABLE A

Property	*Typical Range Values*	*Preferred Range for rollers 120A and 140A*
Tensile Strength@73 F, (ult)/(yld)	15,000-25,000 psi	15,200 psi
Tensile Modulus of Elasticity @ 73 F	420,000 – 1,300,000 psi	430,000 psi
Flexural Strength @ 73 F	12,000 – 33,000 psi	22,000 psi
Shear Strength @ 73 F	14,000 – 15,000 psi	15,000 psi
Compressive Strength, (% Deformation) @73 F	19,000 – 32,000 psi	21,900 psi
Coefficient of Friction, (Dry vs. Steel) Dynamic	0.18 –0.45	0.43 - 0.45
Rockwell Hardness	100 – 120 "M" Scale units	109 "M" scale units
Deflection Temperature @ 66 psi, ¼"	400-420 psi	410 psi
Deflection Temperature @ 264 psi, ¼"	390 – 420 psi	392 psi
Melting Point	400° - 450° F	426 °F

The properties of TABLE A are particularly important since: (a) high values for tensile properties are needed to effectively apply the pressure and tension for curving of stainless steel and titanium rods, and to withstand repeated use; and (b) high values for temperature endurance properties ensure that autoclaving will not deform or compromise the integrity of the rollers 120A and 140A. One such plastic (an amorphous polyetherimide) believed to possess these properties is ULTEM®, manufactured by Ensinger Engineering Plastics having an address of 365 Meadow Lands Blvd., Washington, PA 19301. Thus, in one embodiment of apparatus 10A, ULTEM® may be used for the rod contacting portions of the rollers 120A and 140A, although other materials satisfying the above preferred ranges of TABLE A may also be used.

Still referring to Figs 9A-9C, the ring 426 is sandwiched between two steel metal

rims 430 and 434. Each of the steel rims 430 and 434 contain six threaded bores 438 through which threaded screws 442 are used to connect both rims 430 and 434 together with the ring 426 therebetween. The side of the rim 430 that is exterior to the drive roller 120A contains bore contours that mate with the screw shaft side 446 of the heads of the screws 442, such that when the screws 442 attach the two steel rims 430 and 434 together, the screws 442 are flush with the exterior sides of the drive roller 120A. Both of the rims 430 and 434 also contain a central hexagonal opening 450 that defines the ends of the hexagonal hole 418. Moreover, it is substantially the hexagonal openings 450 that mate with the hexagonal portion of the shaft (not shown) for driving the roller 120A by the gear 80A..

When fully assembled the driving rolling subassembly 44A is shaped to fit the "U" shaped cradle 348 formed in the stationary housing (Fig. 7) so that when operably connected to the threaded shaft 56A, e.g., via the groove 104A (Fig. 12), the subassembly 44A readily moves within the cradle 348 in response to a change in the length of the shaft 56A within the recess 352 as described hereinabove. It is an important aspect of the driving roller subassembly 44A that it is easily detachable from the housing 312 for, e.g., sterilization purposes. In particular, as described above, the frame 382 for the subassembly 44A is formed of a single piece of metal.

Referring to the counter rollers 140A (Fig. 13), these rollers 140A may be composed of the same material as the ring 426 of the driving roller 120A for ensuring that a rod 14 being curved is not marred during the process of curving. Since the counter force applied by driving roller 120A is distributed between the two counter rollers 140A, reinforcing metal rims (such as rims 430 and 434) may not be needed. However, in one embodiment, such rims may be provided for each of the counter rollers 140A.

Each of the counter rollers 140A, and the driving roller 120A includes a respective concave channel 146A and 150A (Figs. 9B and 13) about its circumference for contacting a rod 14during curving. These channels are configured to accommodate rods 14 having a diameter of approximately ¼ to 3/16 of an inch. It is preferred that when a bending force is being applied to a rod 14 by apparatus 10A, that each of these channels 146A and 150A contact at least 1/4 of the circumference of the rod and more preferably

at least 1/3 of the circumference of the rod. By providing such extensive channel contact about each rod curved, it has been determined that abnormalities are not introduced into the surface of the rods 14. In particular, it is believed that by contacting a substantial portion of each rod's circumference during the rod curving process (with a material having the preferred tensile, elasticity and temperature properties of TABLE A hereinabove), the stresses induced into the rods are similar to those that the rods experience during their manufacture (typically via an extruding process), and thus, the surface of the rods do not have surface abnormalities introduced when curved using, e.g., apparatus 10A. It is also important to note that different shapes for the channels 146A and 150A can be used to accommodate rods other than ones with circular cross sections. Thus, for a rod 14 having a hexagonal cross sectional shape, each of the channels 146A and 150A may have a three-sided cross section that mates with a corresponding portion of the rod's hexagonal cross section.

Referring to Fig. 13, each of the counter rollers 140A have a central cylindrical hole 396, wherein a cylindrical shaft 454 is provided and about which the counter roller rotates. Each of the two shafts 454 attaches at its uppermost end 458 to a bearing (not shown) inserted into one of the corresponding holes 462 (Fig. 7) drilled into the upper retaining plate $170A_1$ (more particularly, by drilling from the underneath side 316 through the lower retaining block $170A_2$, thereby also creating a lower corresponding hole 466, and then continuing drilling partially through the thickness of the upper retaining plate $170A_1$). When in place, each such shaft 454 extends between one of the lower holes 466 and a corresponding one of the holes 462. Thus each of the shafts 454 extends through both: (1) the counter roller slot 344 (Fig. 7) immediately above the lower hole 466 for the shaft, and (2) the cylindrical hole 396 of one of the counter rollers 140A, and then into the bearing in the hole 462 immediately above the slot 344. Additionally, the lower end 470 of the shaft 454 is mounted upon a shaft 474. The shaft 474 has a bearing 478 resting on this shaft's top end 482, wherein the bearing is between and contacts both the lower end 470 and the top end 482. Note that the shaft 474 also traverses the interior of a cylindrical spacer 486. The shaft 474 also has a threaded base 490 which mates with the threads of a corresponding one of the bores 324 (Fig. 10).

Fig. 8 shows a stainless steel alignment handle 190A used to grip the end of rods 14 so that during a curving of such a rod by the apparatus 10A, the rod can be maintained in a desired orientation while the rollers 120A and 140A are rolling back and forth along a length of the rod (as described hereinabove. The handle 190A has a hand grip 494 that includes side grips 498 and 502. Each of the side grips 498 and 502 attaches to surgical rod gripping shaft 504 that is perpendicular to side grips. One end of the rod gripping shaft 504 makes up part of the hand grip 494 and the free end 508 has an opening 512. The shaft 504 has a slot 516 extending from the hand grip 494 to approximately 2/3 of the shaft's length toward its free end 508. The portions of the shaft 504 on each side of slot 516 (these portions denoted "jaws" 520 herein) can flex for narrowing the slot 516. The side grip 498 includes a threaded extension 524 (only partially shown) that extends through the shaft 504 and a bearing 528, and then threads into the center of the side grip 502. Thus, by turning the side grip 498 according to arrow 532, the jaws 520 can be brought together thereby narrowing the slot 516. Moreover, if desired, the extension 370 of the adjustment arm 180A can be inserted into the bore 536 for thereby assisting in turning the side grip 498 in the direction of the arrow 532 or in the opposite direction. Note that the adjustment arm 180A is also formed from one piece of stainless steel. The adjustment arm portion gripped by the user during operation is grooved for providing a better grip when twisting or turning the side grip 498 or the adjustment knob 60A during operation of the spinal curving apparatus 10A. The adjustment arm 180A can also be provided in various sizes. Moreover, it is important to note that the alignment handle 190A locks onto the rod 14 so that the user need not manually sustain a gripping force during operation and can thus better keep the alignment of the rod in a particular plane without worry that not enough grip is being applied to keep the rod tightly gripped by the handle.

To use the alignment handle 190A, a user first assures that the side grip 498 is not crimping the jaws 520 toward one another (by partially unthreading the extension 524 from the side grip 502). Subsequently, the user inserts the end of a rod 14 into the opening 512 so that the end of the rod slides toward the side grips 498 and 502. The rod end slides into the opening 512 approximately three eighths of the way toward the side

grips 498 and 502 and then contacts a stop (not shown) on each of the facing sides of the jaws 520, wherein the stops prevent further insertion of the rod into the shaft 504. Since some surgical rods 14 (particularly titanium rods) have at least one end that has a hexagonal shape (e.g., the end has a hexagonal cross section), the stops can include portions that can mate with such a hexagon shaped end of the rod or grip a cylindrical shaped rod end. Once a rod 14 end is fully inserted into contact with the stops, the side grip 498 is twisted in the direction of arrow 532 until the extension 524 is sufficiently threaded within the side grip 502 that the jaws 520 tightly grip the end of the rod 14. Additionally, when the side grip 498 is turned in the opposite direction from arrow 532, the rod 14 slips easily out of the shaft 504. Note that the alignment handle 190A does not damage the surface of the rod being curved and the handle can be easily disassembled for, e.g., sterilization.

In operation, after the rod curving apparatus 10A is sterilized, it is affixed to a relatively flat, even surface such as an surgery table so that hospital personnel can perform the process of rod curving during a spinal surgical procedure on a patient. The weight of the apparatus 10A may be sufficient to prevent substantial movement during operation, but as described hereinabove, an elastomeric or foam pad (not shown) may be provided for mating with base 16A to further increase stability.

To begin the process of rod curving, the user may first determine the desired curve to induce in a surgical rod 14. Portions of the rod 14 to be curved may be marked along the longitudinal extent(s) of the rod, e.g. by a non-marring marker. One end of the rod 14 is then inserted into the opening 512 of the alignment handle 190A. The side grip 498 of the alignment handle 190A is then turned (using the adjustment arm 180A or otherwise) so that the jaws 520 tightly attach about the rod end inserted into the shaft 504 so that the rod can be kept in a desired orientation relative to the rollers 120A and 140A during the rod curving process (e.g., in a single plane having the curve of the rod therein). During the surgical procedure, the user or an assistant may maintain the alignment of the handle 190A so that, e.g., the two grips 498 and 502 remain parallel to the surface upon which the rod curving apparatus 10A is placed while the rod is being curved (via the back and forth motion of the rod between the rollers 120A and 140A as described regarding

the operation of apparatus 10). Additionally, for inducing non-planar curves into the rod 14, once a desired planar portion of a non-planar curve is induced into the rod, the orientation of the alignment handle 190A to, e.g., the surgery table surface can be changed so that additional rod curving is performed in a different plane.

Accordingly, to curve a rod 14 with the apparatus 10A, the rod is first inserted into the apparatus 10A by first rotating the adjustment knob 60A in a counter-clockwise direction so that the shaft 56A pulls the driving roller subassembly 44A further into the recess 352 and away from the counter rollers 140A, thereby increasing the space between the driving roller 120A and the counter rollers 140A until enough space has been created therebetween so that the rod 14 can be engaged by the rollers. Assuming a first planar curve is to be induced into the rod 14 and that the portion of the rod to be curved is clearly identified, the alignment handle 190A is attached to an end of the rod so that the grips 498 and 502 are to remain in a predetermined orientation (e.g., parallel to the surface upon which the rod curving apparatus 10A is placed) during the curving operation. The rod is then inserted into the channels 146A of both counter rollers 140A with the desired orientation maintained. The adjustment knob 60A is then rotated manually (by direct hand turning of the knob, or via the use of the adjustment arm 180A) to cause the shaft end 366 of the shaft 56A to press against the plate 104A, and thereby urge the driving roller subassembly 44A in the direction of arrow 40A (i.e. toward the rod 14). Once the driving roller subassembly 44A contacts the rod 14, the rod enters the channel 150A of the driving roller 120A. To produce a rod curve once the rod 14 is held between the two counter rollers 140A on one side of the rod and the driving roller 120A on the other side, the adjustment knob 60A is rotated (directly or via the adjustment arm 180A) so that shaft 56A moves the driving roller 120A a small increment toward the rod thereby commencing to induce a slight curve into the rod. In particular, upon initial firm contact of the rod by the driving roller 120A, the "small" increment is generally in the range of 1/32 to 1/16 of an inch, and such increments correspond with, e.g., an easily remembered and determined rotation of the adjustment knob 60A such as 1/8 or ¼ of a turn of the knob. Moreover, the indicia 378 provided on the knob 60A also assists an operator in more precisely turning the knob for applying an appropriate curving pressure.

Accordingly, after each desired small incremental deflection of the rod 14 by the driving roller 120A, one of the apparatus 10A operators then commences to rotate the crank 132A to thereby move different portions of the rod's length between the counter rollers 140A. For example, from a center point of where the desired curve is to be located along the rod 14, the crank 132A is operated so that approximately a same length of the rod on either side of the center point is traversed by the driving roller 120A.

As the driving roller subassembly 44A is iteratively and incrementally moved laterally to deflect the rod 14 between the counter rollers 140A, it is important to note that preferably, for each incremental movement of the driving roller 120A toward the rod, the user should not turn the adjustment knob 60A beyond an amount that would cause the rod to deflect beyond an inherent resiliency or elasticity of the rod. That is, for each incremental deflection of the rod, if the current incremental lateral deflecting force was removed, the rod would substantially return to its initial curvature prior to the rod being subjected to the current incremental deflection. For surgical rods 14 made of, e.g., stainless steel or titanium, such a deflection (denoted "resilient deflection" herein) may be attained by a rod deflection of no more than 1/16 of an inch, and more preferably no more than 1/32 of an inch. Moreover, the pitch of the threads on the shaft 56A are such that the ranges 1/16 to 1/32 of rod deflection correspond with, respectively, approximately ¼ to 1/8 of a full 360 degree turn of the adjustment knob 60A. In one method of operation, it is preferred that the adjustment knob 60A be rotated by ¼ turn for stainless steel rods 14, and 1/8 of a turn for titanium rods, which are less malleable.

Thus, after an incremental resilient deflection force has been applied to the rod 14, the user then revolves the crank 132A to urge a predetermined length of the rod through the channels 146A and 150A of the rollers 140A and 120A for being deflected by the driving roller 120A. Thus, iterative application of an incremental resilient deflection force along the longitudinal extent of the rod 14 will ensure a smooth curve in the rod without causing surface anomalies in the rod 14. Note that because of the construction of the housing 312, the user(s) is able to view the rod curving process to determine whether the desired curve is being provided. Moreover, if such a curve becomes unacceptable, the user(s) can easily remove the objectionable portion of the

curve by first, removing the driving roller 120A tension being placed on the rod, rotating the rod so that the alignment handle 190A is turned 180 degrees. Then, by repeatedly alternating between: (a) causing the driving roller 120A to move further in the direction of arrow 40A, and (b) rolling the driving roller 120A over a portion of the rod having the undesirable curve, this undesirable curve can be removed.

To release the rod 14 from the spinal rod curving apparatus 10A, the user may manually (or optionally with the adjustment arm 180A) turn the adjustment knob 60A until the (any) tension placed by the driving roller 120A on the rod is released and the driving roller subassembly 44A is pulled away from the rod. At this point, the rod 14 can be easily extracted from the spinal rod curving apparatus 10A.

The foregoing discussion of the invention has been presented for purposes of illustration and description. Further, the description is not intended to limit the invention to the form disclosed herein. Consequently, variations and modifications commensurate with the above teachings, within the skill and knowledge of the relevant art, are within the scope of the present invention. The embodiments described hereinabove are further intended to explain the best mode presently known of practicing the invention and to enable others skilled in the art to utilize the invention in such or in other embodiments and with various modifications required by their particular application or use of the invention. It is intended that the appended claims be construed to include the alternative embodiments to the extent permitted by the prior art.